

were harvested into phosphate buffer saline (PBS) solution and the concentration of bacterial suspension was adjusted to an optical density of 20 (when diluted 1/20 gives an OD of 1.00+/-0.005 at 600 nm). Bacterial culture supernatant was tested at full strength or serially diluted 1:2 with PBS.

[0032] The following assay was used: Eight μ l of bacterial suspension was mixed with an equal volume of tissue culture supernatant dilution on a glass microscope slide (25x75 mm) at room temperature. In a separate place on the same slide there is a control consisting of bacterial suspension with 8 μ l of PBS (autoagglutination control). The mixture is rocked back and forth continuously and the agglutination is observed at 10 seconds, 30 seconds, 1 minute and 2 minutes. The results are visually scored as follows:

[0033] 4=agglutination in less than 10 seconds with large clumps

[0034] 3=agglutination in less than 30 seconds with large clumps

[0035] 2=agglutination in less than 60 seconds with medium clumps

[0036] 1=agglutination in less than 2 minutes with small clumps

[0037] 0=no agglutination within 2 minutes.

[0038] Results

[0039] At undiluted tissue culture supernatant (estimated at 1 μ g/ml of antibody), no bacterial strains were agglutinated. After concentration of tissue culture supernatant to 20 fold concentration (YM 100 centrifugal ultrafilter, Amicon, Danvers, Massachusetts), only the bacterial strain expressing CFA/I was agglutinated (H10407NM). The monoclonal antibody supernatant was then concentrated 130 fold from original strength and tested. Under these circumstances, the antibody agglutinated all bacteria bearing CS4-CFA/I family proteins.

[0040] The hybridoma identified as 96-109FE8 IH11 has been deposited in the American Type Culture Collection at 10801 University Boulevard, Manassas, Va. 20110-2209 and given the designation ATCC HB-12163.

[0041] As indicated above the antibody may be used for purposes of identifying *E. coli* bearing the CS4-CFA/I protein family. The samples suspected of containing *E. coli* of the CS4-CFA/I protein may be grown by usual methods in the clinical laboratory. The colonies of organisms may then be suspended by the method disclosed above. The suspended organisms are then exposed to a composition containing at least 30 μ g/ml of antibody. In a preferred embodiment, the suspended organisms would be exposed to a composition containing an antibody concentration of 100 to 130 μ g/ml. Appropriate samples would include stools from patients suffering from diarrhea and for testing food and environmental samples for contamination with ETEC *E. coli* organisms.

[0042] The monoclonal antibody (MAB) is useful for identifying members of the CS4-CFA/I family in cultures. Assay kits containing the MAB may be prepared and may contain, in addition to the MAB of the invention, agents for tagging for facilitate identification of the MAB/antigen complex. Such tags include radioactive isotopes, fluorescing agents and colorimetric indicators. Such agents may be attached to solid supports. For example, an ELISA test kit system may be used to identify the MAB/antigen complex.

[0043] Compositions containing the MAB of the invention may be prepared using as a carrier appropriate for addition to a growth media. Saline and other buffered solutions known in the art are appropriate as carriers for the MAB.

[0044] MABs of the invention may also be prepared in pharmaceutically acceptable carrier solutions and may be administered to the infected area to agglutinate the bacteria bearing CS4-CFA/I proteins. Administration would provide means for the compositions to contact the organisms. For example, the compositions could be administered orally in capsules which protect the antibody from destruction in the stomach and duodenum. The compositions are appropriate for use both for short-term prophylaxis and for treatment of ETEC *E. coli* infections by administration of an ETEC *E. coli* agglutinating effective amount of the pharmaceutical composition.

SEQUENCE LISTING

<160> NUMBER OF SEQ ID NOS: 3

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<211> LENGTH: 36

<212> TYPE: PRT

<213> ORGANISM: *Escherichia coli*

<400> SEQUENCE: 1

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20 25 30

Tyr Ser Pro Ala
35